

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RLL-4 04 WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/IB2004/002190	International filing date (day/month/year) 01/07/2004	(Earliest) Priority Date (day/month/year) 01/07/2003
Applicant RANBAXY LABORATORIES LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2004/002190

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/545 A61K9/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/44614 A (PARK JOON WOO ; CHUNG JONG KEUN (KR); KIM HAK HYOUNG (KR); LIM SANG HE) 10 September 1999 (1999-09-10) examples 1,3,5,7,9-14 -----	1-28
X	WO 99/62559 A (SHERMAN BERNARD CHARLES) 9 December 1999 (1999-12-09) examples -----	1-28
X	WO 99/08683 A (SHERMAN BERNARD CHARLES) 25 February 1999 (1999-02-25) examples -----	1-28
Y	US 4 865 851 A (ELLIOTT LEONARD G ET AL) 12 September 1989 (1989-09-12) cited in the application column 2, line 52 - column 3, line 32 examples ----- -/--	1-28

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

14 December 2004

Date of mailing of the international search report

22/12/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Giménez Miralles, J

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2004/002190

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 00/30647 A (RANEBURGER JOHANNES ; BIOCHEMIE GMBH (AT); JENNEWEIN HERWIG (AT)) 2 June 2000 (2000-06-02) page 4, line 9 - line 17 page 9, line 20 - line 31 page 12, line 3 - line 22 tables 1,2 -----	1-28
Y	WO 00/56286 A (SOMANI JITENDRA KRISHAN ; SEN HIMADRI (IN); BHUSHAN INDU (IN); RANBAXY) 28 September 2000 (2000-09-28) examples 1,2 -----	1-28

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Although claim 28 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box II.1

Claims Nos.: 28

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box II.2

Claims Nos.: 1,18 partly; 2

Present independent claim 1 relates to an extremely large number of possible dry powder compositions of cefuroxime axetil, namely all those comprising a granulate containing: 1) the active, 2) "a lubricant", and 3) "a glidant", with no restriction or limitation as to the nature of the lubricant and the glidant. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of said granulates, namely those wherein the lubricant is stearic acid and the glidant is colloidal SiO₂. Other alternatives are not sufficiently disclosed in the application. It follows that claim 1 covers an area broader than justified by the extent of the disclosure and represents an undue generalisation. In particular, it is not shown/demonstrated in the application that the relevant technical problem (bioavailability) is also solved when the granulate comprises talc as glidant, or when it comprises other lubricants, as claimed in claims 5 and 7. In the present case, the claims so lack support and/or the application so lacks disclosure that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the subject-matter as defined above, i.e. claim 1 taken in combination with claim 16, in the sense of example 1.

It is the same for independent claim 18.

Claim 2 lacks clarity (Article 6 PCT). An attempt is made to define the composition by reference to the result to be achieved (bioavailability). Moreover, the definition used is a relative one established by comparison with a certain commercial composition. The lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II, procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2004/002190

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 28
because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 28 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.: 1, 18 partly; 2
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB2004/002190

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9944614	A	10-09-1999	AT 232728 T	15-03-2003
			AU 3277899 A	20-09-1999
			CA 2322432 A1	10-09-1999
			DE 69905452 D1	27-03-2003
			EP 1066040 A1	10-01-2001
			JP 2002505290 T	19-02-2002
			WO 9944614 A1	10-09-1999
WO 9962559	A	09-12-1999	CA 2239331 C	30-11-1999
			AU 3807499 A	20-12-1999
			WO 9962559 A1	09-12-1999
WO 9908683	A	25-02-1999	CA 2209868 A1	15-02-1999
			AT 213416 T	15-03-2002
			AU 8847098 A	08-03-1999
			WO 9908683 A1	25-02-1999
			DE 69803930 D1	28-03-2002
			DE 69803930 T2	17-10-2002
			EP 0996449 A1	03-05-2000
			ES 2172182 T3	16-09-2002
US 4865851	A	12-09-1989	AT 393794 B	10-12-1991
			AT 125988 A	15-06-1991
			AU 607996 B2	21-03-1991
			AU 1615788 A	17-11-1988
			BE 1000956 A5	23-05-1989
			CA 1328405 C	12-04-1994
			CH 675357 A5	28-09-1990
			CN 88102851 A ,B	21-12-1988
			CS 9104033 A3	12-08-1992
			CY 1600 A	03-04-1992
			DE 3816464 A1	24-11-1988
			DK 263288 A	15-11-1988
			ES 2009915 A6	16-10-1989
			FI 882253 A ,B,	15-11-1988
			FR 2615101 A1	18-11-1988
			GB 2204792 A ,B	23-11-1988
			GR 88100317 A ,B	23-02-1989
			HK 106191 A	03-01-1992
			HR 940557 A1	31-08-1997
			HU 47022 A2	30-01-1989
			IE 61693 B1	16-11-1994
			IL 86359 A	15-11-1992
			IT 1219941 B	24-05-1990
			JP 2049587 C	10-05-1996
			JP 7078023 B	23-08-1995
			JP 63303928 A	12-12-1988
			KR 9509097 B1	14-08-1995
			LV 5726 A4	20-04-1996
			MX 11486 A	01-09-1993
			NL 8801236 A ,B,	01-12-1988
			NO 882123 A ,B,	15-11-1988
			NZ 224598 A	29-08-1989
			PH 26015 A	29-01-1992
			PL 272429 A1	20-02-1989
			PT 87474 A ,B	31-05-1989
			SE 466047 B	09-12-1991
			SE 8801813 A	15-11-1988

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB2004/002190

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4865851	A		SG 51491 G SI 8810927 A , B SK 277898 B6 SU 1837876 A3 YU 92788 A1 ZA 8803400 A ZW 5988 A1	23-08-1991 28-02-1997 11-07-1995 30-08-1993 30-06-1990 29-03-1989 04-04-1990
WO 0030647	A	02-06-2000	AU 759517 B2 AU 1654400 A BR 9915694 A CA 2348876 A1 CN 1330546 T CZ 20011845 A3 WO 0030647 A1 EP 1133298 A1 HU 0104412 A2 ID 28615 A JP 2002530338 T NO 20012526 A NZ 511588 A PL 348744 A1 SK 7162001 A3 TR 200101417 T2 US 6727243 B1 ZA 200103927 A	17-04-2003 13-06-2000 14-08-2001 02-06-2000 09-01-2002 15-08-2001 02-06-2000 19-09-2001 29-04-2002 21-06-2001 17-09-2002 23-05-2001 29-08-2003 03-06-2002 08-10-2001 21-11-2001 27-04-2004 15-05-2002
WO 0056286	A	28-09-2000	AT 244560 T AU 3184300 A BR 0009177 A CA 2366617 A1 EP 1165051 A1 ES 2202069 T3 HK 1043540 A1 WO 0056286 A1 PT 1165051 T US 6346530 B1 US 6323193 B1 ZA 200107718 A DE 60003796 D1 DE 60003796 T2 DK 1165051 T3	15-07-2003 09-10-2000 22-01-2002 28-09-2000 02-01-2002 01-04-2004 24-12-2003 28-09-2000 28-11-2003 12-02-2002 27-11-2001 09-05-2002 14-08-2003 03-06-2004 03-11-2003